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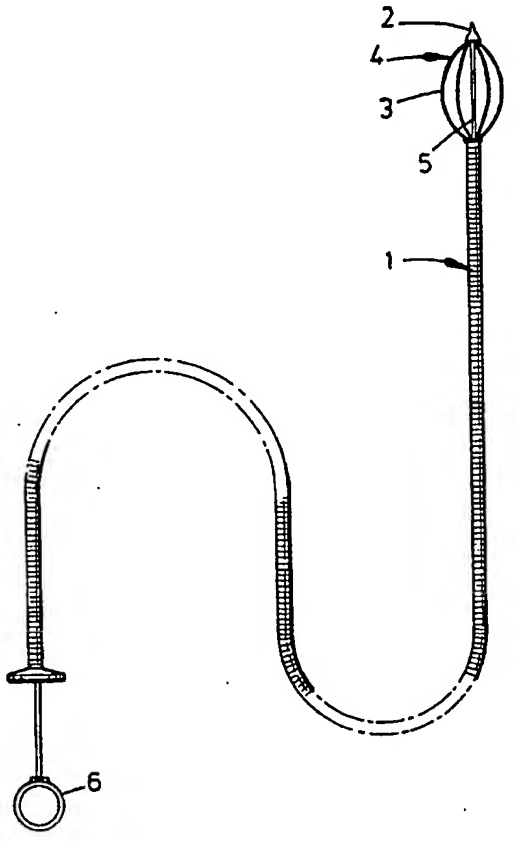
(54) Title: TUNNELLING CATHETER

(57) Abstract

The present invention relates to a diathermy tunnelling catheter device (1). The device (1) has a remotely radially expandable basket (4) with a diathermic cutting and coagulating tip (2) and a plurality of spaced apart diathermic cutting and coagulating bars (3) extending rearwardly from said tip (2). In use the basket (4) is initially advanced into a growth in a radially contracted condition by diathermic cutting with said basket tip (2), the basket (4) is then radially expanded whilst radially cutting diathermically with the cutting bars (3) into the growth, and the basket (4) is then rotated whilst annularly cutting diathermically with the cutting bars (3). Conveniently the device (1) is used via the biopsy channel of an endoscope.



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TUNNELLING CATHETER

This invention introduces a new oesophageal catheter for use endoscopically to tunnel through carcinomas thereby affording simple, effective and inexpensive palliation in cases of advanced oesophageal cancer causing dysphagia. The catheter employs diathermy using high frequency electric current to achieve tunnelling and circumferential coring thus overcoming many of the limitations of LASER therapy. Repeated and frequent application of this form of tunnelling is safe and incurs no added inconvenience to the patient. The implications of this advantage in terms of sustaining palliation cannot be overemphasised.

Results in the management of cancer of the oesophagus have presented little progress over the last few decades. There is therefore much controversy concerning not only the options available for surgical management, but also for non-surgical treatment (radiotherapy, chemotherapy, intubation) as well as other treatments such as tunnelling with LASER rays applied endoscopically.

Oesophageal carcinoma is usually diagnosed when symptons of malignant stenosis appear, which implies advanced disease with a poor prognosis. In the majority of patients, the goal of treatment is therefore palliation with restoration of normal swallowing and good quality of life over the remaining life span. Although endoscopic intubation has overcome many of the problems inherent in surgical intubation, it still remains with considerable morbidity thus favouring tunnelling by LASER rays applied endoscopically. This method however is not widely available besides being very expensive. It is consequently an object of this invention to avoid or minimise one or more of the above disadvantages.

The present invention introduces a tunnelling catheter for diathermy current coring and cutting out of oesophageal carcinoma and which may be presented to the site of the carcinoma via the biopsy channel of a fibreoptic endoscope or by attachment to the body of this scope or via a rigid oesophagoscope.

The present invention provides a diathermy tunnelling catheter device having a remotely radially expandable basket means with a diathermic cutting and coagulating tip and a plurality of spaced apart diathermic cutting and coagulating bars extending rearwardly from said tip, whereby in use of the device the basket means may be initially advanced into a growth in a radially contracted condition by diathermic cutting with said basket tip, the basket then radially expanded whilst radially cutting diathermically with said cutting bars into said growth, and the basket then rotated whilst annularly cutting diathermically with said cutting bars.

Preferably the device of the invention is dimensioned so as to be useable via the biopsy channel of an endoscope and in use is introduced through the biopsy channel of the fibreoptic endoscope to afford two main actions: tunnelling and coring under direct vision. The amount of diathermy tumour resection can be controlled directly by varying the degree of expansion and hence effective diameter of the device thereby allowing a good degree of precision in the application of the tunnelling. This advantage and that of low cost should enable a wide use of the present invention for palliating oesophageal cancer.

Advantageously an electric current is applied to provide electrocoagulation at both the tip and basket bars to

provide haemostasis if necessary. In addition this current may be unipolar or bipolar.

Regarding manufacturing details, the size of the tunnelling catheter may be made in larger sizes for use with rigid oesophagoscopes or for being attached to but not through a fibreoptic endoscope i.e. with the latter being used primarily to provide vision at the site of operation of the tunneling catheter device. The catheter can also be made in sizes to suit various veterinary uses.

The tunnelling catheter may be made in total or in part from metals such as steel, silver, aluminium, titanium etc, or alloys such as stainless steel. Conveniently some or all of the catheter may be made of plastics, silicones and/or natural or synthetic rubber materials. The most preferend substances to be used are Teflon, Dacron,(Trade Names), latex, polyvinylchloride and biocompatible silicones. Advantageously, an antibiotic and/or antiseptic may be incorporated into the catheter's substances and parts.

The tunnelling catheter device of the invention can be remotely controlled from outside of the patient's body to give a variable cutting/coagulating radius.

In use of the device the catheter tip is presented to the surface of the carcinoma with the basket in the collapsed state. The catheter tip is heated by passing a high frequency electric current through its heating element, allowing the catheter to be pushed partially into the blockage. The basket is then progressively expended, accompanied by rotation and backward/forward movement to provide a tunnelling action, ultimately leading to the creation of a complete passageway through

the blockage. The coagulating current delivered to the tip or basket bars may be used to arrest any haemorrhage. Excised tissues may be removed by forceps or flushing into the stomach.

The tunnelling catheter may be in total or in part silver-impregnated or incorporate a silver-impregnated protective sheath. The catheter may be manufactured so as to be suitable for single use (disposable) or several uses (re-useable) after sterilization by ethylene oxide gas or autoclaving.

The overall length of the tunnelling catheter is conveniently from 300mm to 2000mm, preferably 1500-1600mm for use with a fibreoptic scope and 500-600mm for use with a rigid scope.

The outer diameter of catheter generally ranges from 1.5mm to 30mm, preferably from 1.8mm to 2.8mm for use with a fibreoptic scope and 2 to 5mm for use with a rigid scope.

The outer sheath of the catheter may be made as a tube sheath type or coil sheath type. A tube sheath can provide an extremely flexible catheter sheath particularly suitable for use in the upper oesophagus where much movement can be anticipated.

The catheter tip is generally a solid stiff structure, but if desired, can be made more or less flexible. The overall length is preferably from 2mm to 30mm most preferably 5 to 10mm. It may be in the shape of a needle or have a round bodied end. The needle can be pointed or bevelled having a diagonal slant of an angle ranging from 10 to 80°, preferably 30 to 45°.

The body of the catheter tip may be cylindrical, faceted having 3 to 10 surfaces, serrated or uneven with a roughened surface. Advantageously, the tip may be conical or frusto-conical having a base larger than the end.

The handle of the catheter is desirably formed and arranged so as to be substantially ergonomic and provide good grip and handling characteristics that will enable the mechanics of operating the catheter to be effectively applied. The handle can range from 3cm to 20cm in length and 0.5 to 10cm in width. It can be in one or more parts. It can be made of two halves. Advantageously it can incorporate a sliding forward and backward movement mechanism. The handle may also include hinges. When made of many parts, each or all may be fixed or allow the movement of one part onto the other. The handle may have one to five finger accommodating bars, ridges, grooves, holes, rings, or circular bands. Any or all parts of the handle may be cylindrical, circular, band shaped, coil shaped, triangular shaped, square shaped, rectangular shaped, or any other design to suit application. Similarily any part of the handle may be solid or hollowed. Optionally, the handle may incorporate a piston that can be pushed backward and forward to open or close the basket. This piston may have a ring shaped, spherical, rounded, circular, L-shaped, T-shaped or any of other suitably shaped handle for operating. It may be fitted onto the rear or side of the handle.

The handle conveniently incorporates the basket operating mechanism and can also be used to mount the electrical connections for delivering the diathermy operating electric current. Thus the handle may incorporate one or more e.g. up to ten electrical plugs

or sockets which may be flush with the surface or project above it. Alternatively all electric connections may be removed from the handle and built into the body of the catheter.

The basket is generally made up of form 2 to 12 wires or blades that open up circumferentially around a central support pole. The blades may be strips or bands, triangular, rectangular or square shaped in cross section. The surface of these may be smooth, serated, saw-toothed, or roughened in any shape to facilitate cutting into tissues while providing a positive engagement with them. The wires of the basket may be in the form of spring coils or rods. The basket may incorporate both blades and wires. The outer diameter of the collapsed basket is generally from 1.5mm to 10mm, preferably 1.5mm to 2.8mm for use with the fibreoptic scope. The diameter of the fully opened-up basket is generally up to from 25mm to 30mm . The length of the basket generally ranges from 5mm to 100mm, preferably 10 to 30mm, in its closed collapsed configuration.

The basket is normally operated from the handle and is introduced in its closed collapsed configuration, being then opened up under direct vision e.g. by displacement of the catheter sheath down towards the basket end and closed up again by withdrawing this sheath.

The basket will cut into the growth electrically when opened up and will cut off the growth electrically when rotated around optionally in combination with forward and backward movements.

The principles of surgical diathermy are well known in the art and further information is avalable from standard reference books such as "Encyclopedia of

Medical Devices and Instrummentation" published by John Wiley & Sons, New York etc (1988) and other sources, and accordingly need not be described here in detail.

Briefly diathermy operates by producing an alternating current with wavelengths in the radio frequency range. This current passes through the patient's tissues from the active electrode, which may be of various shapes, to the indifferent (neutral) electrode, which is usually a metal or foil plate approximately 15 X 15cm in size. As this current passes through the tissues there is a heating effect beneath each electrode. The indifferent electrode has a large contact area and therefore heating is reduced to a minimum and is dissipated rapidly. The active electrode being small will concentrate heat in the tissues adjacent to it. The current intensity determines whether a coagulating, fulguration or electro - sectioning effect is produced.

The circuit of the diathermy machine being generally similar to that of a simple radio transmitter will usually oscillate at a frequency between 400kHz (Kilocycles) and 3MHz (megacycles). Oscillators used in earlier diathermy machines incorporating the standard spark - gap principle which provide a frequency of around 500kHz may be used. This would provide excellent coagulation but would cut only by increasing the intensity to a high - power output. Also, valve oscillators of a frequency range of up to 3MHz may be used. This can be in the form of two circuits: with a cutting circuit operated by a valve oscillator and a coagulating circuit operated by a spark-gap oscillator. Diathermy generators of power outputs up to 1 kW may be employed. The use of transistors as oscillators rather than valves is generally preferred.

The quality of coagulation or cutting generally depends on the wave form presented by the diathermy machine, with a smooth sine wave giving the desired cutting while an interrupted burst of current provides the desired coagulation depending on the frequency of these bursts and the length of the gap between each burst. The spark-gap machine generallly gives bursts of damped oscillation of a frequency of approximately 10kHz. When this interuption of current is superimposed on the sine wave oscillation, the coagulation quality is comparable to that of the spark-gap machine. In order to provide an adequate intensity of current the amplitude of each wave should be increased in portion to the length of each burst of current. Thus the doubled circuit may be dispensed with.

Blending the current may be provided by a twin-circuit diathermy where the blender switch brings both circuits into action at the same time with the result that the active electrode produces a cutting effect as well as a coagulating effect as it passes through the tissues. Conversely, a solid state transistorised diathermy machine can be used to provide a blended current from a single circuit by taking the setting halfway between the pure sine wave for cutting and repeated short bursts for coagulation. This provides the advantage of subjecting the patient to only the normal power output of a single circuit. Thus electro-sectioning can be provided by cutting with a valve or transistorised oscillator to ensure minimal surrounding tissue damage or cutting with a blended current if moderate degrees of surrounding coagulation is desirable.

The diathermy machine should normally be earthed to the floor to avoid build up of electrical potential which could discharge in the form of a spark of static

electricity. It may be advantageous to monitor the contact of the plate electrode to patient by measuring the potential difference between the input and output leads.

The overall power output of the diathermy machine is preferably restricted to from 400 to 500 kW.
The diathermy generator may conveniently be provided by valve oscillating machines, double - circuit spark and valve machines, transistorised solid state diathermies and spark-gap generators.

A foot pedal switch or finger switch may be used to activate the diathermy set, i.e. activating the operating electrode to start the diathermy.

To ensure that the plate is in electrical continuity with the diathermy generator, its cable is preferably designed to have an internal circuit so that if any point between the plate and the diathermy machine is disconnected then an alarm will sound which should also inactivate the circuit of the machine. This may not be necessary with earth-free circuits since the diathermy will be non-operated when the patient is not in contact with the indifferent electrode. Thus, earth-free circuits may also be used for the purposes of the present invention.

The electric connections to the diathermy machine may be placed on any part of the handle. The active electrode socket may be designed in any convenient way to enable the current to flow from the diathermy machine to the catheter tip and basket. This socket transmits the electric current from the machine directly to the tunnelling catheter. It may be flush flat with the handle surface or project above it. The active

electrode may be plugged in, screwed-in, clipped-on or fitted into the socket in any convenient way through one or more points of contact. The handle may have a finger switch to activate the diathermy set. Conversely this may be provided by a foot pedal. The indifferent electrode plate is preferably stuck, strapped or attached in any way onto the patients lower limb, but other sites may also be used.

After the oesophagoscope has been introduced and the tumour assessed with or without biopsy, the tunnelling catheter is introduced into the oesophagus and placed in direct contact with the tumour. The active electrode is connected to the catheter's handle then the diathermy machine is switched on. The coagulating and cutting currents are generally set in the range from 20 to 90, preferably 30 to 60 standard diathermy apparatus cutting power units. During use the diathermy machine makes a noise which can be clearly heard to indicate it is working and the current is flowing. The coagulating and cutting currents are used as already described. Repeated sessions of tunnelling at three to seven day intervals may be necessary to achieve the desired tumour coring and tunnelling.

Further preferred features and advantages of the invention will appear from the following detailed description of the use of a tunnelling catheter device of the invention illustrated with reference to the accompanying drawings in which:

Fig.1 is general view of a preferred embodiment;

Fig.2 is a detail sectional view showing mounting of the basket; and

Figs.3 to 5 show some alternative handles.

Patients suitable for this techinque are those who have

advanced oesophageal cancer not suitable for surgery and who present with dysphagia thus requiring some form of intervention to enable them to swallow food comfortably. The patient is endoscoped under parenteral sedation (using benzodiazepines or midazolam with or without narcotic analgesics such as pethidine) and a throat spray with xylocaine in the left lateral position. Biopsies of the oesophageal lesion may be taken first, then the oesophageal tunnelling catheter 1 is introduced and placed in direct contact with the apparent oesophageal lumen and the cutting diathermy current switched on. The tip 2 of the catheter while being heated by the passage of a high frequency electric current through its heating element is advanced through the lesion for a short distance sufficient to allow the bars 3 of the catheter's basket 4 to cut through tumour tissue when opened up. The basket 4 is then expanded using the axial control wire 5 and operating handle 6 connected thereto, while cutting current is being applied, to advance the bars 3 redially outward into the tumour. The basket 4 is then rotated to core out the tumour by cutting through the tissue between the basket bars 3 to cut away the tissue entrapped inside the basket 4. Sufficient tunnelling is carried out at the proximal end of the tumour before advancing the basket 4 down the growth and repeating the procedure. By a combination of radial cutting into the tumour and circumferential rotation to cut off tissue, the oseophageal lumen can be tunnelled through down to the stomach. Any obvious tissue mass lying free in the oesophageal lumen can be picked up by the forceps or flusehed down the into the stomach. Obviously bleeding points can be electrocoagulated by the tip or basket bars.

Following this procedure and once the patient recovers from the sedation he/she is allowed oral intake of fluids for six hours and when these fluids have been well tolerated, solid food is permitted. The procedure may be repeated as frequently as deemed necessary.

Diathermy tunnelling of oesophageal cancer has been successfully applied to the clinical situation without any obvious morbidity or mortality. The procedure should be open without any exclusions to all those oesophageal carcinoma patients who require palliation for their dysphagia. This method is simple, safe, reliable, inexpensive and may be applied repeatedly. It incurs no additional inconvenience to the patient and enables an expeditious return to oral intake of food comfortably. The further advantage of being much more inexpensive and simpler than LASER therapy should allow its wider use clinically.

It will be understood that various modifications may be made to the above described embodiment without departing from the broadest scope on the present invention. Thus for example a wide variety of remote control operations handle mechanisms may be used including: systems with first and second relatively displacable finger rings or other finger engagement formations which may simply be relatively displacable longitudinally of the device, so as to provide a more or less direct longitudinal compression of the basket resulting in radial expansion, or may be relatively displacable in other dimensions e.g. by compressing or pulling laterally towards each other, conveniently against a return force exerted by resilient biasing means, spaced apart finger engagement portions and use one or more of links, levers, gears and other well known mechanisms for converting relative

displacement into a suitable form for transmission to the basket members. In addition hydraulic circuit means and/or electromechanical device may be used for transmitting required control movements to the basket in generally known manner. Conveniently the diathermic cutting and coagulating power supply control means are also provided on the handle means but this is not essential and they may be formed and arranged so as to be operable remotely from the handle means e.g. via a foot operated interface.

CLAIMS

1. A diathermy tunnelling catheter device having a remotely radially expandable basket means with a diathermic cutting and coagulating tip and a plurality of spaced apart diathermic cutting and coagulating bars extending rearwardly from said tip, whereby in use of the device the basket means may initially be advanced into a growth in a radially contracted condition by diathermic cutting with said basket tip, the basket then radially expanded whilst radially cutting diathermically with said cutting bars into said growth, and the basket then rotated whilst annularly cutting diathermically with said cutting bars.

2. A device according to claim 1 wherein said bars are in the form of angularly spaced apart flexible elongate members extending generally along the longitudinal axis of the catheter device and coupled at opposite end portions to a central axial support so as to be axially movable relative thereto, at at least one of their end portions.

3. A device according to claim 2 wherein first end portions of said elongate members remote from said tip are coupled together via an annular member disposed around said central axial support.

4. A device according to claim 3 wherein an elongate tube extends around the central axial support between the basket means and a remote handle means.

5. A device according to claim 4 wherein said remote handle means has relatively displacable portions connected directly or indirectly, to respective ones of

the central axial support and the tube so as to provide relative longitudinal displacement thereof.

6. A device according to any one of claims 1 to 5 wherein said bars are provided with cutting edges.

7. A device according to any one of claims 1 to 6 wherein said bars are formed and arranged for positively engaging tumour tissue.

8. A device according to any one of claims 1 to 8 wherein said basket means has an elongate bowden - cable type control means formed and arranged for remotely radially expanding said basket means.

9. A device according to any one of claims 1 to 8 which device includes a diathermy electrical power supply.

10. A device according to claim 1 for use in the excision of oesophogeal carcinoma tissue.

11. A method of excising oesophogeal carcinoma tissue comprising the steps of:
providing a diathermy tunnelling catheter device according to claim 9;
advancing the tip into said tissue with diathermic cutting;
radially expanding said basket means with radial diatheric cutting of the bars into said tissue; and
rotating the expanded basket with annular diathermic cutting of the bars into said tissue.

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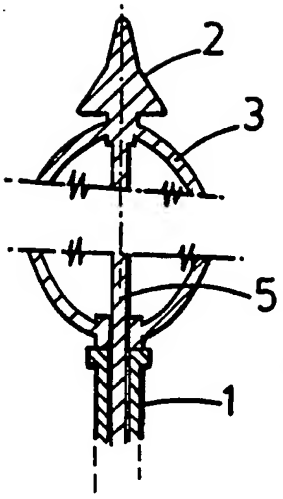


FIG. 2

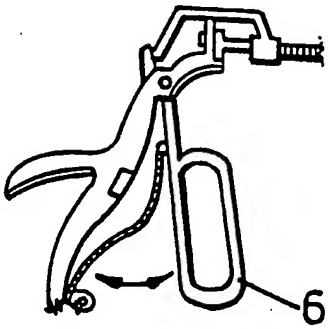
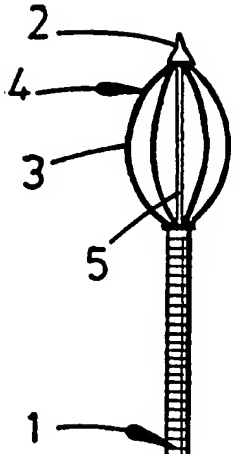


FIG. 3



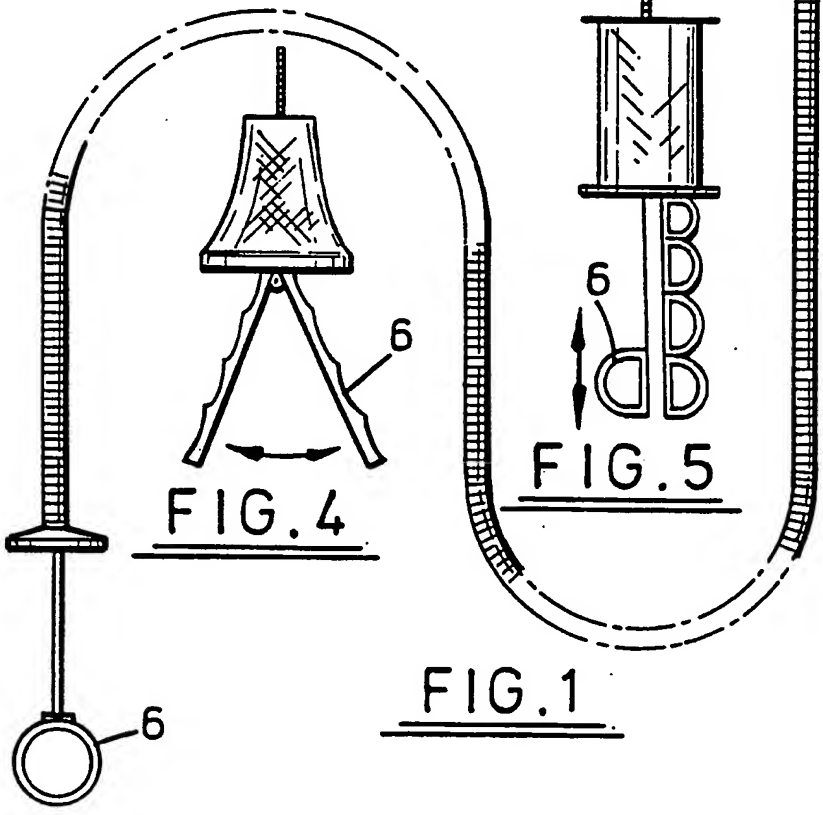


FIG. 4

FIG. 5

FIG. 1

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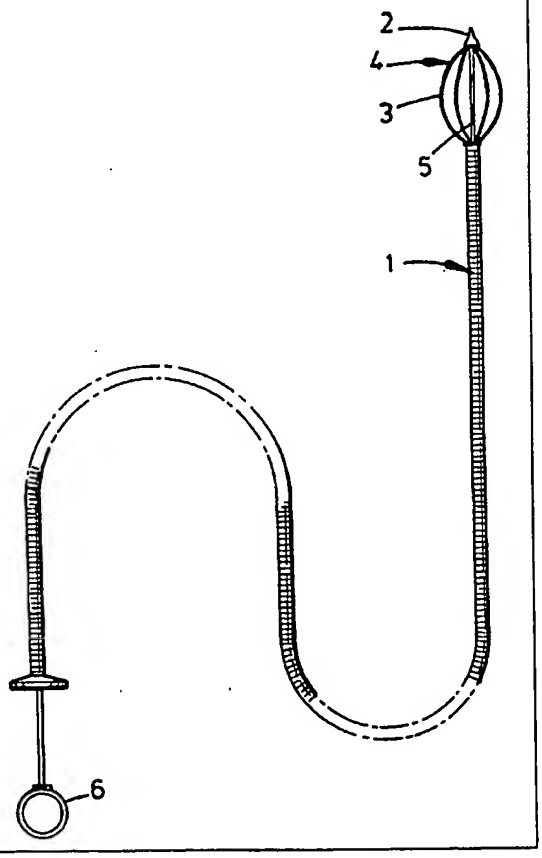

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39 A61B17/22

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B. FIELDS SEARCHED

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IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,4 885 003 (HILLSTEAD) 5 December 1989 see column 5, paragraph 1 -paragraph 5	1-10
Y	US,A,5 030 201 (PALESTRANT) 9 July 1991 see abstract; figures 1,2,6	1-10
A	WO,A,90 07909 (APPLIED UROLOGY) 26 July 1990 see page 4, line 22 - line 29 see page 7, line 5 - line 7; figures 3-6	1
A	EP,A,0 117 519 (THEERMANN) 5 September 1984 see page 14; figure 6 see page 16, paragraph 2	1
A	US,A,5 224 945 (PANNEK) 6 July 1993	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search
14 December 1994

Date of mailing of the international search report
23. 12. 94

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB94/01536

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11
because they relate to subject matter not required to be searched by this Authority, namely:
see Rule 39.1 (iv) PCT

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ational Application No
PCT/GB 94/01536

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4885003	05-12-89	NONE		
US-A-5030201	09-07-91	NONE		
WO-A-9007909	26-07-90	AU-A-	5098290	13-08-90
EP-A-0117519	05-09-84	DE-A-	3306213	23-08-84
		DE-A-	3320984	13-12-84
US-A-5224945	06-07-93	NONE		